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|---|-----------|--|
| (51) International Patent Classification ⁵ : A61K 7/50 | A1 | (11) International Publication Number: WO 90/13283 (43) International Publication Date: 15 November 1990 (15.11.90) |
| (21) International Application Number: PCT/GB90/00700 (22) International Filing Date: 4 May 1990 (04.05.90) (30) Priority data: 347,971 5 May 1989 (05.05.89) US Not furnished 28 July 1989 (28.07.89) US (71) Applicant (for AU GB only): UNILEVER PLC [GB/GB]; Unilever House, Blackfriars, P.O. Box 68, London EC4P 4BQ (GB). (71) Applicant (for all designated States except AU GB): UNILEVER NV [NL/NL]; Burgemeester s' Jacobplein 1, P.O. Box 760, NL-3000 DK Rotterdam (NL). | | (72) Inventors: GREEN, Alan, Paul ; 16 Grandview Circle, County of Hunterdon, Flemington, NJ 08822 (US). McFARQUHAR, Barbara ; 1231 Alicia Avenue, County of Bergen, Teaneck, NJ 07666 (US). PAREDES, Rosa ; 8309 Grand Avenue, County of Hudson, North Bergen, NJ 07047 (US). MELLETT, Marianne ; 540 Fairview Avenue, Westwood, NJ 07675 (US). OSMER, Frederick, Silvio ; 5 Citroen Way, County of Morris, Parsippany, NJ 07054 (US). (74) Agent: THOMAS, Susan, Margaret; Unilever plc, Patent Division, Unilever House, Blackfriars, P.O. Box 68, London EC4 5BQ (GB). (81) Designated States: AT (European patent), AU, BE (European patent), BR, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> |
| (54) Title: AQUEOUS BASED PERSONAL WASHING CLEANSER (57) Abstract An aqueous based personal washing product is disclosed which when used has good cleaning ability and is particularly mild to the skin. The free flowing liquid product is particularly adapted for facial washing and contains acyl ester of isethionic acid salt, long fatty acids and moisturizer component, and preferably a co-active surfactant. | | |

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AQUEOUS BASED PERSONAL WASHING CLEANSERTechnical Field

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The present invention is in the field of aqueous based, surfactant containing, mild cleansers, providing good foaming, moisturizing and cleaning, without excessive harshness.

20

The use of moisturizers in traditional washing bars is severely limited by processing constraints. Usually bars with a high content of moisturizer are sticky and cannot be easily stamped. Some of the difficulties of formulating a good personal washing product with high levels of moisturizers were eliminated by using liquid products to avoid the stamping problem.

25

Moisturizers have also been found to inhibit lathering. However, lathering is desirable for washing products. Further, a high concentration of moisturizers while being desirable for mildness and skin benefit has a tendency to de-stabilize liquid products.

30

It was thus desirable to formulate an aqueous based

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product containing high levels of moisturizers in combination with high levels of mild surfactants to result in a substantially stable personal washing product which is exceptionally mild to the skin; and having excellent lathering characteristics which also leaves the skin
5 feeling smooth, silky, and moisturized.

Background

10 Japanese Patent JP-A-63/243,200 discloses a detergent composition containing a combination of specified acyl isethionates, higher fatty acids and N-acylglutamic acid salts. US 4 556 510 and 4 617 148 both disclose liquid
15 soaps containing polymeric thickeners along with several other surfactants including optionally sodium cocoyl isethionate. US 4 495 079 discloses a therapeutic facial skin cleanser composed of selected surfactant mixtures and active ingredients.

20 There have been many different approaches to the problem of producing an aqueous based mild cleanser containing high levels of emollients/moisturizers together with combinations of mild surfactants having good viscosity, good stability, and high lathering
25 characteristics. None of these approaches has been completely satisfactory. In many cases, stability is sacrificed to improve viscosity, or mildness is de-emphasized to improve cleaning ability or moisturizing is minimized to improve lathering.

30 Disclosure of the Invention

According to the present invention there is provided a liquid aqueous based skin cleansing composition
35 characterised in that it comprises

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(i) at least 3wt% acyl esters of isethionic acid salts, said esters being predominantly C₈ to C₂₂ acyl isethionates;

5 (ii) at least 2wt% of at least one long chain fatty acid having a major proportion of C₁₆ or above; and

(iii) at least 2wt% of a moisturizer component;

10 wherein the weight ratio of said acyl esters to said fatty acid ranges from about 1:0.1 to about 1:10, and soap is present in an amount from 0 to 5% by weight of the composition.

15 The presently defined aqueous based composition containing acylisethionates, fatty acid, and moisturizer component in specified amounts and ratios can provide a fluid aqueous based cleansing and moisturizing product characterized by its mildness, good lathering properties,
20 acceptable viscosity and stability while substantially eliminating many of the problems of the art. Preferably a co-active surfactant is additionally present in an amount at least 2wt% with respect to the total composition.

25 The inventive composition can have the advantages of mildness, good moisturizing, good lathering, and excellent long term stability. Other standard ingredients such as polymeric thickeners, preservatives, further co-surfactants, sequestrants, foam boosters, and the like
30 may also be employed to advantage.

Preferably the composition comprises

(i) 3 to 20wt% said acyl esters of isethionic acid;
35

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(ii) 2 to 15 wt% said long chain fatty acid(s);

(iii) 2 to 20wt% said co-active surfactant;

(iv) 2 to 15% said moisturizer component.

5

Suitably the composition comprises at least 5wt% of said at least one long chain fatty acid, at least 5wt% of said co-active surfactant and at least 5wt% of said moisturizer component.

10

The formulation may suitably contain the following general ingredients provided an appropriate viscosity is achieved:

15

| <u>Ingredients</u> | <u>wt%</u> |
|--------------------|----------------|
| acylisethionate | 3-20% |
| fatty acids | 2-15% |
| moisturizer | 2-15% |
| co-surfactant | 2-20% |
| preservative | 0.1-1% |
| sequestrant | 0.01-0.1% |
| standard additives | 3-15% |
| water | <u>balance</u> |
| | 100 |

20

25

Acylisethionate

30

A critical component of the formulations of the present invention is a non-soap anionic surface active agent. Particularly suitable agents for the present invention are the C_8-C_{22} acyl isethionates. These esters may be prepared by the reaction between alkali metal isethionate and mixed aliphatic fatty acids having from 8

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to 22 carbon atoms and an Iodine Value of less than 20.
In one embodiment of the invention at least 75% of these
mixed fatty acids should preferably have from 12 to 18
carbon atoms and up to 25% should have from 8 to 10 carbon
atoms.

5

Another suitable syndet is that of alkyl glycerol
ether sulfonate. Alkyl chains for this surfactant are
from C₈ to C₂₂, preferably C₁₀ to C₁₈. It is envisaged
that the present compositions could be prepared containing
10 alkyl glycerol ether sulfonate in place of or as well as
the acyl isethionate.

Co-active surfactant

15

A number of anionic, nonionic, cationic and
amphoteric surfactants may be employed as the co-active.
In copending case US Serial Number 340,185 filed on
April 19, 1989, co-active combinations in bars with acyl
isethionates are disclosed. Among suitable anionic
20 co-actives are the alkyl sulfates, alkyl ether sulfates,
alkyl ether sulfonates, sarcosinates, sulfosuccinates,
taurates and combinations thereof. Among suitable
amphoteric co-actives may be included alkylbetaines,
amidopropyl betaines, amidopropyl sultaines and
25 combinations thereof.

The relative amounts of isethionate esters to
co-actives will preferably range in the weight ratio of
30 about 20:1 to about 1:1, preferably from about 5:1 to
about 2:1, optimally about 3:1.

Alkyl ether sulfates will be of the general formula
R-O(CH₂CH₂)_nOSO₃-M⁺ wherein R ranges from C₈-C₂₀ alkyl,
35 preferably C₁₂-C₁₅ alkyl, n is an integer from 9 to 40,

preferably from 10 to 20, optimally about 12, and M^+ is a sodium, potassium, ammonium or triethanolammonium cation. Typical commercial co-actives of this variety are listed in the Table below:

| | | | | |
|----|------------------|---------------------------|----------------------|---------------------------|
| 5 | <u>Trademark</u> | <u>Chemical Name</u> | <u>Physical Form</u> | <u>Manu- facturer</u> |
| 10 | Alkasurf ES-60 | Sodium Laureth Sulfate | Paste | Alkaril |
| | Cycloryl TD | TEA Laureth Sulfate | Paste | Cyclo |
| 15 | Standapol 125-E | Sodium Laureth-12 Sulfate | Liquid | Henkel |
| | Cedepal TD407MF | Sodium Trideceth Sulfate | Paste | Miranol |
| 20 | Standapol T | TEA Lauryl Sulfate | Liquid | Henkel |

25 Alkyl ether sulfonates may also be employed in the present composition. Illustrative of this category is a commercial product known as Avenel S-150 commonly known as a sodium C_{12} - C_{15} Pareth-15 sulfonate.

30 Another co-active type suitable for use in the present composition is that of the sulfosuccinates. This category is best represented by the monoalkyl sulfosuccinates having the formula:
 $RO_2CCH_2CH(SO_3-Na^+)COO-M^+$; and amido-MEA sulfosuccinates of the formula: $RCONHCH_2CH_2O_2CCH_2CH(SO_3-M^+)CCO-M^+$; wherein R
 35 ranges from C_8 - C_{20} alkyl, preferably C_{12} - C_{15} alkyl and M^+

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is a sodium, potassium, ammonium or triethanolammonium cation. Typical commercial products representative of these co-actives are those listed in the Table below:

| | <u>Trademark</u> | <u>Chemical Name</u> | <u>Physical Form</u> | <u>Manufacturer</u> |
|----|------------------|---|----------------------|---------------------|
| 5 | | | | |
| | Emcol 4400-1 | Disodium Lauryl Sulfosuccinate | Solid | Witco |
| 10 | Schercopol CMSNa | Disodium Cocoamido MEA Sulfosuccinate | Liquid | Scher |
| | Emcol 4100M | Disodium Myristamido MEA Sulfosuccinate | Paste | Witco |
| 15 | | | | |
| | Schercopol | Disodium Oleamido MEA | Liquid | Scher |
| 20 | Varsulf S13333 | Disodium Ricinoleamido MEA Sulfosuccinate | Solid | Scherex |

25 Sarcosinates may also be useful in the present composition as a co-active. This category is indicated by the general formula $RCON(CH_3)CH_2CO_2-M^+$, wherein R ranges from C_8-C_{20} alkyl, preferably $C_{12}-C_{15}$ alkyl and M^+ is a sodium, potassium, ammonium or triethanolammonium cation.

30 Typical commercial products representative of these co-actives are those listed in the Table below:

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| <u>Trademark</u> | <u>Chemical Name</u> | <u>Physical Form</u> | <u>Manu- facturer</u> |
|--------------------|-------------------------------|--------------------------|---------------------------|
| Hamposyl L-95 | Sodium Lauroyl Sarcosinate | Solid | W.R. Grace |
| Hamposyl TOC-30 | TEA Cocoyl Sarcosinate | Liquid | W.R. Grace |

Taurates may also be employed in the present composition as co-actives. These materials are generally identified by the formula $\text{RCONR}^1\text{CH}_2\text{CH}_2\text{SO}_3\text{-M}^+$, wherein R ranges from $\text{C}_8\text{-C}_{20}$ alkyl, preferably $\text{C}_{12}\text{-C}_{15}$ alkyl, R^1 ranges from $\text{C}_1\text{-C}_4$ alkyl, and M^+ is a sodium, potassium, ammonium or triethanolammonium cation. Typical commercial products representative of these co-actives are those listed in the Table below:

| <u>Trademark</u> | <u>Chemical Name</u> | <u>Physical Form</u> | <u>Manu- facturer</u> |
|------------------|---------------------------------|--------------------------|---------------------------|
| Igepon TC 42 | Sodium Methyl Cocoyl Taurate | Paste | GAF |
| Igepon T-77 | Sodium Methyl Oleoyl Taurate | Paste | GAF |

Within the category of amphoterics there are three general categories suitable for use in the present compositions. These include alkylbetaines of the formula $\text{RN}^+(\text{CH}_3)_2\text{CH}_2\text{CO}_2\text{-M}^+$, amidopropylbetaines of the formula $\text{RCONHCH}_2\text{CH}_2\text{CH}_2\text{N}^+(\text{CH}_3)_2\text{CH}_2\text{CO}_2\text{-M}^+$, and amidopropyl sultaines of the formula $\text{RCONHCH}_2\text{CH}_2\text{N}^+(\text{CH}_3)_2\text{CH}_2\text{SO}_3\text{-M}^+$, wherein R ranges from $\text{C}_8\text{-C}_{20}$ alkyl, preferably $\text{C}_{12}\text{-C}_{15}$ alkyl, and M^+ is a sodium, potassium, ammonium or triethanolammonium

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cation. Typical commercial products representative of these co-actives are found in the Table below:

| | <u>Trademark</u> | <u>Chemical Name</u> | <u>Physical Form</u> | <u>Manu- facturer</u> |
|----|------------------|--------------------------------|----------------------|---------------------------|
| 5 | Lonzaine C | Cocamidopropyl Betaine | Liquid | Lonza |
| 10 | Lonzaine CS | Cocamidopropyl Hydroxysultaine | Liquid | Lonza |
| | Lonzaine 12C | Coco-Betaine | Liquid | Lonza |
| 15 | Schercotaine MAB | Myristamidopropyl Betaine | Liquid | Lonza |
| | Velvetex OLB-50 | Oleyl Betaine | Paste | Henkel |
| 20 | | | | |

Within the broad category of liquid co-actives, the most effective are the alkyl sulfates, alkyl ether sulfates, alkyl ether sulfonates and sulfosuccinates.

25

Long chain fatty acids

Free fatty acids of 8-22 carbons are desirably incorporated within the compositions of the present invention. These fatty acids are present to operate as lather enhancing agents and as skin feel, lubricity, and creaminess enhancers. The agents may be selected from fatty acids of carbon atoms numbering 8-18 in an amount up to about 15% by weight of the composition. The most important agent is a stearic acid/palmitic acid mixture.

- 10 -

Levels of these acids can range from 1% up to 15% by weight so as to provide a major proportion of C₁₆ and above. A combination of principally palmitic and stearic acids of about 45wt% stearic and 55wt% palmitic is preferred.

5

Moisturizer component

Moisturizers are included to provide skin conditioning benefits and to improve the mildness of the product. The selection of the levels and types of moisturizers to be incorporated into the product is done in such a manner as not to affect adversely the stability of the product or its in-use characteristics, and still deliver good moisturization and lather.

10

15

The term "moisturizer" is often use synonymously with the term emollient, and is then meant to describe a material which imparts a smooth and soft feeling to the skin surface.

20

One way of reducing water loss from the stratum corneum is to deposit on the surface of the skin a layer which reduces the rate of evaporation. Another method is to add hygroscopic substances, which will retain water, to the stratum corneum, to make this water available to the stratum corneum.

25

Both types of moisturizers as well as mixtures of these are operative in the present invention. Some examples of moisturizers are long chain fatty acids, liquid water-soluble polyols, glycerin, propylene glycol, sorbitol, polyethylene glycol, ethoxylated/propoxylated ethers of methyl glucosé and ethoxylated/propoxylated ethers of lanolin alcohol. Thus the present composition

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requires the presence of long chain fatty acids and in addition another moisturizer.

5 The moisturizers useful in the present invention, including the long chain free fatty acids, are preferably used at a level of in total about 5% to 35% by weight of the composition. The preferred and more preferred levels of total moisturizers are, respectively, 5wt% to 30wt% and 8wt% to 20wt%. The most preferred moisturizer combination is a mixture of propylene glycol and a combination of
10 stearic and palmitic acids having a weight ratio of glycol to acid of 1:3 to 5:1. The moisturizer combination, at the above levels, provides superior moisturization. The high level of moisturizer can provide enhanced mildness.

15 The moisturizer to soap weight ratios when soap is used are preferably 7 to 1 and, more preferably, 4 to 1.

20 Other moisturizers are compounds found naturally in the stratum corneum of the skin.

Moisturizers also include petrolatum, mineral oil, beeswax, silicones, lanolin and oil-soluble lanolin derivatives, saturated and unsaturated fatty alcohols and
25 various animal and vegetable oils.

Soaps

30 Soaps may optionally be included in the compositions of the present invention as a structurant.

Soaps can be used at levels of preferably about 5% and most preferably at a level of about 2% by weight. The soaps may be added neat or made in situ via adding a base,
35 e.g., NaOH to convert free fatty acids.

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Other ingredients

Free sodium isethionate in an amount of about 1% to about 7% by weight affects stability and viscosity and may also affect mildness and can suitably be included in the present composition. It can either be added as a separate ingredient or may be present in commercially available acyl isethionate.

Standard additives such as colouring agents, opacifying agents e.g. TiO_2 , thickeners e.g. carbopols may be used with the present compositions in varying amounts to insure appropriate benefits.

Sequestering agents such as EDTA, ethylene diamine tetraacetic acid trisodium salt of EHDP [disodium (1-Hydroxyethylidene) biphosphate] or mixtures of these in amounts ranging from 0.01 to as high as 1.0wt% preferably about 0.01 to 0.05wt% may be used.

Preservatives such as antimicrobials or antimould/fungus agents may be used. Examples of these are methyl paraben (p hydroxymethylbenzoate); propyl paraben (p hydroxypropylbenzoate); and Dowicil 200 [N-(3-chlorallyl) Hexaminium chloride]. These and other similar materials may be used in amounts of about 0.1wt% to about 0.5wt% and may be used separately or in combination.

Antioxidants such as, for example, butylated hydroxytoluene (BHT) may be used advantageously in amounts of about 0.01wt% or higher if appropriate.

Viscosity

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Viscosity of the formulation is measured with a Brookfield cone and plate H.B.D.V. II viscometer at 2 min., 25°C and a shear rate of $1s^{-1}$. The viscosity of the present compositions can vary from about 100 cps to about 30,000 cps or higher if desirable, and will preferably be from about 10,000 cps to 15,000 cps.

Lather

Lather evaluations are done by applying a two gram sample to the hands, followed by applying six millilitres of water. The hands are then placed palm to palm and rotated five times in a circular motion in order to dissolve the product. The product is then "worked up" by rotating the hands ten times. The resulting lather is measured by immersing the hands in a distilled water bath and lowering a funnel, whose neck has been fitted with a graduated cylinder, over the hands, so that the volume of lather can be measured.

Selected combinations of acyl isethionate and stearic/palmitic acid can show improved lathering.

Embodiments of the Invention

The invention will now be illustrated with reference to the following Examples, which are by way of example only. Unless otherwise indicated all percentages are by weight.

Example I

An aqueous based formulation embodying the present invention contains the following ingredients in the indicated amounts:

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| | <u>Ingredients</u> | <u>wt%</u> |
|----|-------------------------------|------------|
| | Sodium cocoyl isethionate | 11% |
| | Stearic acid | 8% |
| 5 | Propylene glycol | 10% |
| | Sodium isethionate | 5% |
| | TEA lauryl sulfate | 5% |
| | Sodium soap * (82/18) | 2.5% |
| | Sodium alkylbenzene sulfonate | 2% |
| 10 | Fragrance | 0.4% |
| | Methylparaben | 0.20% |
| | Propylparaben | 0.10% |
| | Dowicil 200 | 0.10% |
| | EDTA | 0.02% |
| 15 | EHDP | 0.02% |
| | BHT | 0.008% |
| | Water to | 100.00% |

* A mixture of 82wt% tallow soap and 18wt% coconut soap.

Process

A batch of the present formulation is prepared as follows. Some of the numbers are approximate since commercial solutions vary in content.

A submix is first prepared by charging 1451.1kg (3,200 lbs.) of propylene glycol to a tank with agitation. 916 kg (2,019.20 lbs.) of sodium isethionate is added with slow speed agitation. 532.5kg (1,174.40 lbs.) of a slurry containing 293kg (645.9 lbs.) of sodium alkyl benzene sulfonate is then added and mixing is continued to ensure uniformity. 1814.5kg (4,000 lbs.) of a 40% solution of triethanolamine lauryl sulfate is then added and mixed

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until uniform at a temperature of about 26.6°C to 32.2°C (80 to 90°F). This submix is then set aside for future use.

5 6159 kg (13,577.76 lbs.) of deionized water is heated and charged to the main mixing tank and is maintained at about 82.2°C (180 degrees F). The previously prepared submix is then slowly added with slow speed agitation. 2871 kg (6,329.6 lbs.) of a commercial preparation of sodium cocoyl isethionate is then added. This material
10 contains 55wt% sodium cocoyl isethionate; 30wt% long chain fatty acids; 8wt% sodium isethionate and 7wt% miscellaneous; 348.5kg (768 lbs.) of soap; 29kg (64 lbs.) of methyl paraben, 14.5 kg (32 lbs.) of propyl paraben, 7.5 kg (16.32 lbs.) of EDTA and 5 kg (10.56 lbs.) of EHDP
15 are added with mixing at about 5 minute intervals. 273 kg (601.60 lbs.) of stearic acid is then added and agitation is increased as necessary to achieve uniformity. The entire batch is then mixed at 79.4°C to 82.2°C (175° to
20 180° F) to ensure uniformity. The batch is then slowly cooled to about 46.1°C (115°F). 14.5 kg (32 pounds) of Dowicil is mixed into 18 kg (65 lbs.) of cold deionized water and this mixture is added to the batch. A previously prepared homogeneous fragrance mix composed of
25 58 kg (128 lbs.) of perfume and 1 kg (2.56 lbs) of BHT are added and mixed into the batch. The entire batch is then mixed and cooled to reach a suitable viscosity.

30 Thickener slurries may, of course, optionally be used at appropriate points. These slurries may contain suitable materials such as polymers, e.g. carbopol, gums and the like.

35

EXAMPLE 2

This Example illustrates the equivalency in mildness between a composition A embodying the present invention and a 50% aqueous slurry of a commercial non soap detergent bar B. The percentages of B are approximate. Table I lists the two compositions.

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TABLE IFormulations

| | | <u>A %wt/wt.</u> | <u>B %wt./wt.</u> |
|----|---|------------------|-------------------|
| 5 | Sodium Cocoyl Isethionate | 10.95 | 25.0 |
| | Stearic Acid * | 8.01 | 10.0 |
| 10 | Na Soap (82/18 tallow/ coconut) | 2.40 | 5.5 |
| | Sodium Alkylbenzenesulfonate | 2.02 | 1.0 |
| 15 | Sodium Isethionate | 5.09 | 2.4 |
| | TEA Lauryl Sulfate | 5.00 | -- |
| 20 | Propylene Glycol | 10.00 | -- |
| | Cosmedia Guar C-261 (guar gum/thickener) | 0.50 | -- |
| 25 | Methylparaben | 0.20 | -- |
| | Propylparaben | 0.10 | -- |
| | Dowicil 200 | 0.10 | -- |
| 30 | Viscasil 60M (silicone) | 1.00 | -- |
| | Perfume | 0.10 | 0.5 |
| 35 | Lower Fatty acid | -- | 1.5 |

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Miscellaneous solids -- 1.7
& electrolytes

Water to 100.00 to 100.00

5 * C₁₄ = 3%; C₁₆ = 50%; C₁₈ = 47%

Both formulations were tested by Flex Wash. Table II lists the Flex Wash outcome which confirms the equivalent mild behaviour of Formulation A to a 50% slurry of a commercial bar whose major ingredient is sodium cocoyl isethionate.

TABLE II

15

Flex Wash Test

| <u>Sample</u> | <u>Mean Scores *</u> | <u>Mean Rank</u> |
|-----------------|--------------------------|------------------|
| <u>Erythema</u> | <u>Endpoint Erythema</u> | |
| A | 1.385 | 13.62 |
| B | 1.385 | 13.38 |

20

25 Statistical Analysis

Rank Score: P = 0.9580
(Wilcoxon 2 sample)

* Mean end point scores are the mean of the evaluation scores at which the first arm received a grade "2" or greater erythema score or at the completion of nineteen washes.

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The Flex Wash Test

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5 The Flex Wash procedure consists of four daily 60 second washes of the antecubital fossa (flex area of elbow). This method was designed to produce erythema quickly. Erythematous response varies only slightly with temperature and humidity fluctuations making the protocol suitable for year round testing.

10 Approximately 15 panelists were used as the test population. Panelist flex areas must be free of any skin condition (eczema, dryness, irritation, cuts or abrasions). Anyone taking antihistamines, anti-inflammatory drugs or topical, oral or injectable cortisone on a regular basis was excluded from the study. The panel was divided into two subgroups which were
15 balanced for left handedness. Group I was assigned composition "A" for the left flex and "B" for the right flex. Group II reversed the order.

20 Following an evaluation, the panelist was instructed to moisten the left flex area. A sponge was dampened with tap water (100 ppm calcium/magnesium ions). A fixed amount of test product was applied to the sponge. The "dosed" sponge was placed in the panelist's right hand. The panelist then washed the left flex area for exactly 60
25 seconds (approximately 120 strokes). Thereupon, the flex was rinsed and patted dry. This washing procedure was repeated on the right arm with the appropriate composition. Washing by this procedure was repeated 4 times daily for four days and 3 times on the fifth day for
30 a total of 19 washes. Treatment times were scheduled 1.5 hours apart. Each test site was evaluated immediately prior to washing and 4 hours after the third daily wash.

35 One trained assessor evaluated test sites prior to each wash and 4 hours after the third wash of the fifth

- 20 -

day for a total of 20 evaluations. The grading scale was as follows:

- 0 - no erythema
- 0.5 - barely perceptible erythema
- 1 - mild spotty erythema/no oedema
- 1.5 - mild/moderate erythema/with or without oedema
- 2 - moderate confluent erythema/with or without oedema or vesiculation

Each site was treated in the prescribed method until a grading of "2" or greater was attained or 19 washings had been completed. When a score of "2" or greater was attained the treatment was discontinued on that flex. The final score was then carried through for all remaining evaluations. The remaining flex was washed until either a grading of at least "2" or 19 treatments were attained, whichever was first. In this Example, the final grading is the sum total of grade scores for 20 assessments per panelist averages over the scores from all panelists. Thus, theoretically the average score could range from 0 to 38; the lower value indicating absolutely no skin irritation with the latter being severe. In practice, scores generally range from 15 to 30.

Arm Wash

The objective is to compare the levels of irritation and/or dryness of two products on skin by assessing the changes in skin condition during exaggerated use conditions. Changes are assessed both visually and instrumentally.

The subject/panelist is in the age group of 18-55 years. The subject must have been screened for soap

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sensitivity and found to be sensitive to the screening solution. The target site must be free of cuts and abrasions and have a grade "0" for both erythema and dryness following a two week preconditioning period.

5 The subject must refrain from using creams, lotions or other types of moisturizing products over the target body area (the forearms) throughout the duration of the test.

10 Subjects with allergies to soap and fragrances, a history of skin disease or currently undergoing treatment for a dermatologic condition or who did not respond positively to the soap sensitivity screening test as well
15 as subjects currently within the 2 weeks prior to the start date, taking antiinflammatory agents are excluded.

Experimental Design

20 Subjects are required to precondition their skin using the conditioning product supplied under normal use conditions. This preconditioning period is two weeks in length immediately prior to the onset of the study. Use
25 of the preconditioning product will continue throughout the study for all bathing and showering.

30 A group panel of 30 subjects is randomly selected based on an acceptable skin condition score for dryness and erythema established at baseline. The panel is randomly balanced for age and sex and each panelist is
35 assigned a subject number. Laboratory wash treatments are for two morning sessions and two afternoon sessions over a four day test period. The fifth day includes two morning washes. The time interval between treatment and final assessment are standard within the panel.

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Visual and tactile assessments are conducted immediately before each wash treatment to evaluate and compare changes in skin condition. A final visual assessment is conducted.

5 The target site is the volar surface of the forearm from the antecubital fossa (flex area) to the wrist.

10 Subjects are supplied with blinded product for all home bathing and are instructed to avoid washing the test site during the test week.

Wash Procedure

15 All wash treatments are conducted by a technician. Both forearms are washed simultaneously taking care to exert equal pressure/force to each arm. Technicians alternate their treatment groups at each wash interval.

20 1. Using water maintained at 32°C (90°F) each forearm is wet thoroughly from the flex area to the wrist.

25 2. The product is placed on a wet pad and spread over the pad. The treated pad is then placed on the designated arm and is then gently glided up and down the volar surface of the forearm for two minutes.

30 3. The arm is rinsed under running water for 30 seconds and patted dry gently with a soft disposable towel.

Visual Assessment

35 A trained skin evaluator conducts all visual assessments. The forearms are assessed for erythema and dryness immediately prior to each wash treatment. A five

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point scoring scale (0-4) is used to assess skin condition for both dryness and erythema. Half point increments are used to denote slight differences between arms or for responses not warranting a full point increase.

5

Dryness**Erythema**

0 - None

0 - None

1 - Slight flaking

1 - Mild erythema

10

2 - Moderate flaking/scaling

2 - Moderate confluent
erythema3 - Marked scaling, slight
fissuring

3 - Marked erythema

4 - Severe scaling, fissuring

4 - Deep erythema

15

Forearms are treated until a grade "3" or greater erythema or dryness develops (end point score). Once an end point score is attained treatment of both sites is discontinued. The final visual assessment is conducted approximately three hours after the last wash.

20

The arm wash test described above was run comparing the following two products. Formulation C embodies the present invention, whilst Formulation B is a comparative product.

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Table III

| | <u>Ingredients</u> | <u>Form. C</u> | <u>Comparative</u> |
|----|------------------------------|----------------|--------------------|
| | | <u>% wt/wt</u> | <u>Form. B</u> |
| 5 | | | |
| | Sodium Cocoyl Isethionate | 10.95 | 25 |
| | Stearic Acid | 8.01 | 10 |
| | Sodium Soap | 2.40 | 5.5 |
| 10 | Sodium Alkylbenzenesulfonate | 2.02 | 1.0 |
| | Sodium Isethionate | 5.09 | 2.4 |
| | TEA Lauryl Sulfate | 5.00 | -- |
| | Propylene Glycol | 10.00 | -- |
| | Methylparaben | 0.20 | -- |
| 15 | Propylparaben | 0.10 | -- |
| | Dowicil 200 | 0.10 | -- |
| | Fragrance | 0.10 | 0.5 |
| | Lower Fatty acid | | 1.5 |
| | Miscellaneous solids | -- | 1.5 |
| 20 | & electrolytes | | |
| | Water | to 100.00 | to 100.00 |

As in Table I, Formulation B represents a 50% slurry of a commercial bar. The percentages are thus approximate. Formulation C has no guar gum or viscasil. The test was run to compare the mildness/irritation potential of cleanser C with a 50% slurry of a commercial bar B. The test site was treated with one gram of slurry B or 0.5 gram of the facial cleanser C.

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Table IVRESULTS OF ARM WASH TEST:

| | | | |
|----|-------------------------|-----------|-----------|
| 5 | MEAN SCORES * | END POINT | END POINT |
| | | ERYTHEMA | DRYNESS |
| | Slurry B | 1.000 | 1.531 |
| | Product C | 1.250 | 1.563 |
| 10 | MEAN RANK: | ERYTHEMA | DRYNESS |
| | Slurry B | 13.88 | 15.81 |
| | Product C | 19.13 | 17.19 |
| 15 | STATISTICAL ANALYSIS OF | | |
| | RANK SCORES: | p=0.0981 | p=0.6844 |

(Wilcoxon 2 sample)

20 * Mean end point scores are the mean of the evaluation scores at which the first arm receives a grade "2" or greater erythema score or grade "3" dryness score or at the completion of nineteen washes.

25 The results indicated no significant difference ($P \leq 0.05$) between Product B slurry and Product C based on the mean rank erythema and dryness scores at end point. Product C was somewhat more irritating than the slurry.

30

SUMMARY

The inventive composition has been evaluated in clinical studies against a slurry of a commercial bar.

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In the Flex Wash against the slurry, the scores for the present composition were identical to the slurry scores for erythema. In the Arm Wash test, the present composition scores for dryness were very close to those of the slurry. There were some negative differences between the present composition score and the slurry for erythema in the Arm Wash.

Table V

| | <u>Slurry</u> | <u>Present Composition</u> |
|--------------------|---------------|----------------------------|
| Flex Wash Erythema | 1.385 | 1.385 |
| Arm Wash Dryness | 1.531 | 1.563 |
| Arm Wash Erythema | 1.000 | 1.250 |

Facial Wash Study

The test group includes 35 subjects/panelists in the age group of 18 to 55 years. The subject must have no history of allergies or skin diseases. Panelists must refrain from using facial creams, lotions or other type of moisturizing products on their faces throughout the duration of the test period. Upon admittance to the study, each subject is provided with (2) bars of commercial soap to be used at home for a two week period prior to the start of testing.

Eligible panelists are assigned test products selected at random to equal a Right/Left or Left/Right balance in product assignment to each half-face side.

Assigned Groups Include:

Group I Right half, Code B Group II Right half, Code A

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Left half, Code A

Left half, Code B

Procedure

5 The schedule of wash treatments includes a single
facial wash conducted both in the morning and afternoon
and for four consecutive test days or a total of 7 wash
treatments. Panelists are instructed not to use anything
on their faces except to wash with warm water and face
10 cloth.

Each subject has their face washed in the following
manner by a technician:

15 a) Wet both sides of the face 10 seconds

b) An abundant lather is worked up for each test
product for 10 seconds by gently rubbing a moistened pad
35 to 37.7°C (95 to 100°F) made of soft non-woven cotton
20 cloth in each product.

c) The lathered pads are then massaged slowly but
firmly over the cheek area using a counter-circular motion
with a pad in each hand, washing for 60 seconds then
25 rinsing with running water 35 to 37.7°C (95 to 100°F) for
10 seconds. This procedure is repeated a second time to
equal a two-minute wash treatment. The face is then
rinsed for 60 seconds with warm water and patted dry using
soft disposable terry towels.

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Evaluation and Scoring System

a) Panelist self-assessment of facial skin
condition is conducted once during the study.

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b) Panelists will assess their facial condition based on a global evaluation of appearance and feel of skin, comparing both left and right sides of the face.

5 c) Trained assessors also assess the skin condition using a grade score scale ranging from 0 to 2.5; independent parameters of evaluation will include softness and feel, degree of dryness, erythema and roughness on the face.

10 d) Panelists and trained assessors assess both sides of their face and the same hand at all times. The inside forearm of the opposite arm will represent a reference control site for softness.

15 Data and Statistics

The raw data scores are analysed employing a paired t-test and parametric statistical design.

20 A half face test was conducted as described above on 35 panelists with "normal" skin types to compare the formulation of the invention and a commercial liquid soap. After one week screening period, the test period consisted of 8 wash treatments over a 4 day span with 9 evaluations
25 done. The first evaluation was made prior to the first wash treatment and the ninth evaluation was made on the morning of the fifth day. The panelists have refrained from the use of anything but water on their faces during
30 the study. Evaluations of various attributes were made by one expert judge and each panelist over the test period.

The top line results of this study are summarized in Table VI. The table indicates those evaluations for which
35 statistically significant differences (with 95%

- 29 -

confidence) were detected for each of the expert judge and panelist questions.

The composition A specified in Table I was compared to a commercial liquid soap with the following results.

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TABLE VI

Results of Facial Wash

| <u>Attribute</u> | <u>Judges' *</u> | | <u>Commercial</u> | | <u>Panelists *</u> | | <u>Commercial</u> | |
|------------------|----------------------|--|-------------------|--|----------------------|--|-------------------|--|
| | <u>Composition A</u> | | <u>Liquid</u> | | <u>Composition A</u> | | <u>Liquid</u> | |
| Overall Softness | 24 ** | | 1 | | 17** | | 4 | |
| Erythema | 26.1** | | 40.9 | | | | | |
| Dryness | 23.4** | | 43.6 | | 3.6** | | 5.1 | |
| Roughness | 22.7** | | 44.3 | | 3.4** | | 4.9 | |
| Tightness | | | | | 3.0** | | 4.1 | |
| Burning | | | | | 2.1** | | 3.3 | |
| Stinging | | | | | 2.2** | | 2.9 | |
| Itching | | | | | 2.9** | | 3.6 | |

* The judge's scores reflect mean ranks for all panelists. The panelist's scores are individual scores based on a 0-9 scale.

** Significant at the 95% confidence level.

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In the Half Face test against the Commercial Liquid, Composition A is significantly (95% confidence level) preferred by both judges and panelists for overall softness. The judges also rated the Composition A significantly (95% confidence level) better than the Commercial Liquid for dryness, roughness, tightness, burning, itching and stinging.

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Claims

1. A liquid aqueous based skin cleansing composition characterised in that it comprises:

- 5 (i) at least 3wt% acyl esters of isethionic acid salts, said esters being predominantly C₈-C₂₂ acyl isethionates;
- (ii) at least 2wt% of at least one long chain fatty acid having a major proportion of C₁₆ or above; and
- 10 (iii) at least 2wt% of a moisturizer component;

wherein the weight ratio of said acyl esters to fatty acid ranges from about 1:0.1 to about 1:10, and soap is present in an amount from 0 to 5% by weight of the composition.

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2. Composition according to claim 1 comprising additionally at least 2wt% of co-active surfactant.

20 3. Composition according to claim 2 comprising

- (i) 3 to 20 wt% said acyl esters of isethionic acid;
- 25 (ii) 2 to 15wt% said long chain fatty acid(s);
- (iii) 2 to 20wt% said co-active surfactant;
- (iv) 2 to 15wt% said moisturizer component.

30 4. Composition according to claim 2 or claim 3 comprising at least 5wt% of said at least one long chain fatty acid, at least 5wt% of said co-active surfactant and at least 5wt% of said moisturizer component.

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5. Composition according to claim 1 wherein the acyl esters of isethionic acid comprise at least 75% C₁₂ to C₁₈ acyl isethionates.

5 6. Composition according to claim 1 wherein the said long chain fatty acids comprises a combination of about 45wt% stearic acid and 55wt% palmitic acid.

7. Composition according to claim 2 wherein the co-active surfactant is one or more components selected
10 from the group comprising anionic, nonionic, cationic and amphoteric surfactants.

8. Composition according to claim 7 wherein the co-active surfactant includes an anionic surfactant and is
15 selected from the group comprising alkyl sulfates, alkyl ether sulfates, alkyl ether sulfonates, sarcosinates, sulfosuccinates, taurates and combinations thereof.

9. Composition according to claim 7 wherein the co-active surfactant includes an amphoteric surfactant and
20 is selected from the group comprising alkylbetaines, amidopropyl betaines, amidopropyl sultaines and combinations thereof.

25 10. Composition according to claim 2 wherein the weight ratio of the said acyl esters of isethionic acid to the said co-active surfactant lies in the range of from about 20:1 to about 1:1.

30 11. Composition according to claim 1 wherein the said moisturizer component is selected from the group comprising liquid water-soluble polyols, glycerin, propylene glycol, sorbitol, polyethylene glycol,
35 ethoxylated/propoxylated ethers of methyl glucose and

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ethoxylated/propoxylated ethers of lanolin alcohol, and mixtures thereof.

12. Composition according to claim 1 comprising 1 to 7wt% sodium isethionate.

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13. Composition according to claim 1 having a viscosity at a shear rate of $1s^{-1}$ of from about 100cps to about 30,000 cps.

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INTERNATIONAL SEARCH REPORT

PCT/GB 90/00700

International Application No

| | | |
|--|---|---|
| I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶ | | |
| According to International Patent Classification (IPC) or to both National Classification and IPC | | |
| Int.Cl. 5 A61K7/50 | | |
| II. FIELDS SEARCHED | | |
| Minimum Documentation Searched ⁷ | | |
| Classification System | Classification Symbols | |
| Int.Cl. 5 | A61K | |
| Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸ | | |
| III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹ | | |
| Category ¹⁰ | Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹² | Relevant to Claim No. ¹³ |
| A | EP,A,0176330 (UNILEVER) 02 April 1986 see page 21, example 5 see page 22, table IX see claims 1-8 --- | 1, 2, 7, 8, 12 |
| A | EP,A,0217250 (HENKEL KOMMANDITGESELLSCHAFT AUF AKTIEN) 08 April 1987 see columns 1 - 6 --- | 1, 2, 7-9 |
| A | FR,A,2594692 (L'OREAL) 28 August 1987 see page 4, example 1 see page 5, example 3 see claims 1-5, 9 --- | 1, 2, 7, 11 |
| <p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> | | |
| IV. CERTIFICATION | | |
| Date of the Actual Completion of the International Search | | Date of Mailing of this International Search Report |
| 16 OCTOBER 1990 | | 19. 10. 90 |
| International Searching Authority | | Signature of Authorized Officer |
| EUROPEAN PATENT OFFICE | | M. Peis M. PEIS |

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

GB 9000700

SA 36572

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on

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| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| | | AU-A- 4767785 | 10-04-86 |
| | | JP-A- 61085497 | 01-05-86 |
| | | US-A- 4695395 | 22-09-87 |
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